



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JUN 18 2004

Dr. Norman Valdivia
Chief of the Meat Inspection Service
Dirección General de Protección y Sanidad Agropecuaria
Ministry of Agriculture and Forestry
Gobierno De Nicaragua
Managua, Nicaragua

Dear Dr. Valdivia:

The Food Safety and Inspection Service completed an on-site audit of Nicaragua's meat inspection system. The audit was conducted from November 4 through 19, 2003. Comments from Nicaragua have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by facsimile at 202-690-4040, or by email at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Alan Hrapsky, Attaché, US Embassy, San Jose

Ervin Leiva, Agric Specialist, US Embassy, Managua, Nicaragua

Mauricio Rivas, Commercial Attaché, Embassy of Nicaragua

Jeanne Bailey, FAS Area Officer

Amy Winton, State Department

Linda Swacina, Deputy Administrator, FSIS

Karen Stuck, Assistant Administrator, Office of International Affairs, FSIS

Donald Smart, Director, Review Staff, FSIS

Sally Stratmoen, Director, International Equivalence Staff, OIA, FSIS

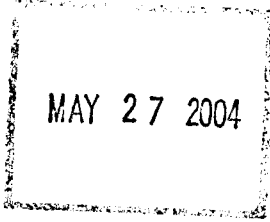
Clark Danford, Director, IEPS, OIA, FSIS

Mary Stanley, Director, IID, OIA, FSIS

Shannon McMurtrey, IES, OIA, FSIS

Country File

FINAL



MAY 27 2004

FINAL REPORT OF AN AUDIT CARRIED OUT IN
NICARAGUA COVERING NICARAGUA'S MEAT INSPECTION
SYSTEM

NOVEMBER 4 THROUGH NOVEMBER 19, 2003

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority, the Office of Animal Health
CFU	Colony-Forming Units
DSA	<i>Dirección de Salud Animal</i> , the Office of Animal Health
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
MAG-FOR	<i>Ministerio Agropecuario y Forestal</i> (Ministry of Agriculture, Food, and Forestry)
MVO	Medico Veterinario Oficial (Equivalent to Veterinary Inspector-In-Charge of an establishment)
PR/HACCP	Pathogen Reduction/ Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedure(s)
<i>Salmonella</i>	<i>Salmonella</i> species

1. INTRODUCTION

The audit took place in Nicaragua from November 4 through November 19, 2003.

An opening meeting was held on November 4, 2003, in Managua with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the audit itineraries, and requested additional information needed to complete the audit of Nicaragua's meat inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA, the Ministry of Agriculture, Food, and Forestry (*Ministerio Agropecuario y Forestal, or MAG-FOR*).

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, two laboratories performing analytical testing on United States-eligible product, and three slaughter and processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	4	Managua
Laboratories		2	Residues and Microbiology
Meat Slaughter & Processing Establishments		3	Managua, Juiualpa, and Nandaime

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in Nicaragua's inspection headquarters. The third part involved on-site visits to the three slaughter and processing establishments certified to export to the United States. The fourth part involved visits to two government laboratories. The government-owned and -operated National Laboratory of Biological Residues in Managua was conducting analyses of meat samples for Nicaragua's national residue control program. The government-owned and -operated National Laboratory of Veterinary Diagnostics in Managua was analyzing meat samples for the presence of generic *E. coli* and *Salmonella* species.

Program effectiveness determinations of Nicaragua's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) programs and the testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including the testing program for *Salmonella* species. Nicaragua's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted food safety and public health. The auditors assessed how inspection services are carried out by Nicaragua and also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During the opening meeting, the auditors explained that Nicaragua's inspection system would be audited against two standards. First, the auditors would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, and testing for generic *E. coli*. Second, the auditors would audit against any equivalence determinations that have been made for Nicaragua. There are currently no equivalence determinations for Nicaragua.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
<http://www.fsis.usda.gov/OPPDE/FAR/index.htm>.

The last FSIS audit of Nicaragua's inspection system was conducted in April 2003. The following deficiencies were identified:

- Nicaragua had not enforced the FSIS requirement for sampling sites on beef carcasses for sampling for generic *E. coli*. During the FSIS audit in April 2003, this was a

repeat finding (in all three establishments) from the previous audit in June 2002 (in two of the three establishments).

- The FSIS audit in April 2003 noted that the sampling technique for generic *E. coli* was improper (not aseptic) in all three establishments. The FSIS audit in June 2002 had noted the same deficiency in two of the three establishments.
- The FSIS audit in April 2003 noted cross-contamination in one of the three establishments.
- The FSIS audit in April 2003 noted a personal hygiene problem in one of the three establishments: an employee failed to wash his hands after handling cartons before handling meat.
- The FSIS audit in April 2003 noted inadequate pre-operational sanitation controls in one establishment: residues from the previous day's production were present on the controls of processing equipment.

6. MAIN FINDINGS

6.1 Government Oversight

6.1.1 CCA Control Systems

The sanitation, slaughter and processing inspection procedures and standards, and the legal authority to enforce these requirements are outlined and specified in two legal documents. The first is the *Reglamento de Inspeccion Sanitaria de la Carne para Establecimientos Autorizados* (Regulation of Sanitary Inspection of Meat for Authorized Establishments), which went into effect in 1958 and was revised in 1990. It has been revised again and the revision is open for public comment. The new revision is expected to go into effect during calendar year 2004. The sections that provide the authority for enforcement are Articles 205, 206, and 207. The second is *Ley No. 291: Ley Basica de Salud Animal y Sanidad Vegetal* (Law No. 291: Basic Law of Animal Health and Vegetable Health), which went into effect June 3, 1998.

In each of the three establishments certified for U.S. export, the MAG-FOR staffing consists of one *Medico Veterinario Oficial* (MVO, or Official Veterinary Medical Officer) and six *Inspectores Ayudantes* (Auxiliary Inspectors). The MVOs are rotated among the three establishments every two years.

The procedure for initial establishment certification for U.S. export is outlined in Chapter III, Sections 10 through 14 (Articles 4 through 10) of the Regulation of Sanitary Inspection of Meat for Authorized Establishments and also (the HACCP requirements) in Law No. 291: Basic Law of Animal Health and Vegetable Health, Articles 22 and 40. In

brief, according to the *Reglamento*, when the management in an establishment has officially requested approval to export to the U.S., the following steps are taken:

1. The establishment must comply with the *Reglamento* and the *Ley*.
2. The establishment must develop a residue control program.
3. The establishment must develop a microbiological control program (for *E. coli*, *Salmonella*, and *Listeria*).
4. The establishment must develop an SSOP program.
5. The establishment must develop a complete HACCP program.

When the above steps are complete, an official veterinarian from the Department of Inspection and HACCP Certification reviews the documentation and conducts an on-site audit. All the information and the report of the audit are then reviewed by the Chief Veterinary Meat Inspector before he recommends final approval. The final approval is then granted jointly by the Chief of the Department of Inspection and HACCP Certification and the Director of the *Direccion de Salud Animal* (Department of Animal Health).

6.1.2 Ultimate Control and Supervision

The MVOs in the three establishments are supervised directly by the Chief Veterinary Meat Inspector, who also conducts the monthly supervisory reviews. The Chief Veterinary Meat Inspector answers to Chief of the Department of Inspection and HACCP Certification and the Director of the Department of Animal Health.

The activities and responsibilities of the official in the position of Chief Veterinary Meat Inspector are stipulated in Articles 22 and 23 of the Regulation of Sanitary Inspection of Meat for Authorized Establishments.

6.1.3 Assignment of Competent, Qualified Inspectors

The Chief Veterinary Meat Inspector is responsible for training each hired employee and/or for ensuring that the hired employee has the required pre-employment training. On-the-job training is provided in the establishments by the official veterinarians and is supervised by the Chief Veterinary Meat Inspector. All MVOs and auxiliary inspectors receive three months of specific training in meat inspection before assuming official responsibilities in export establishments.

The three MVOs have, respectively, 13, 20, and 25 years of inspection experience in export slaughter establishments. The MVOs are rotated among the three establishments every two years. There is also a designated relief MVO ready to fill in for illness or annual leave. If an inspector is ill, the inspector from the local establishment pool with the most experience substitutes. Whenever an auxiliary inspector resigns, a replacement is transferred from another export establishment.

In all three establishments, the MVOs had had recent specific HACCP training courses. In all establishments, copies of the United States PR/HACCP regulations were present and the MVOs were documenting their evaluations of establishment compliance with the HACCP and SSOP requirements.

All MVOs and auxiliary inspectors appeared to be adequately trained; however, in all three establishments, there were deficiencies in inspection controls regarding enforcement of FSIS requirements.

6.1.4 Authority and Responsibility to Enforce the Laws

The MVOs have full authority to retain and condemn product, reject equipment, suspend production, and withhold inspection. The authority to delist is granted in Article 19 of the Regulation of Sanitary Inspection of Meat for Authorized Establishments and lies jointly with the Chief Veterinary Meat Inspector, the Chief of the Department of Inspection and HACCP Certification, and the Director of the Department of Animal Health.

6.1.5 Adequate Administrative and Technical Support

Nicaragua's Ministry of Agriculture has adequate administrative and technical support and has the ability to support a third party audit.

6.2 Headquarters Audits

The auditor conducted a review of inspection system documents at the headquarters of the inspection service. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as cysticercosis.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of seizure and control of noncompliant product.

No concerns arose as a result of the examination of these documents.

6.3.1 Audits of Regional Inspection Offices

There are no regional or district meat inspection offices: the MVOs in the three establishments are supervised directly by the Chief Veterinary Meat Inspector.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited all three slaughter/processing establishments currently certified by Nicaragua as eligible to export to the United States. None was delisted by Nicaragua because of failure to meet basic U.S. requirements. Two received Notices of Intent to Delist (NOID) from MAG-FOR because of deficiencies involving SSOP and HACCP implementation. These establishments may retain their certification for export to the United States provided that all deficiencies noted during the audit are corrected within 30 days of the dates when the establishments were audited.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratories were audited:

- The government-owned and -operated *Laboratorio Nacional de Residuos Químicos y Biológicos* (National Laboratory for Chemical and Biological Residues) in Managua.
- The government-owned and -operated *Laboratorio Nacional de Diagnosticos Veterinarios* (National Laboratory of Veterinary Diagnostics) in Managua.

The findings in these laboratories are discussed in Section 11.3 (Testing for generic *E. coli*), 12 (RESIDUE CONTROLS), and 13.2 (Testing for *Salmonella* species) of this report.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focused on five areas of risk to assess Nicaragua's meat inspection system. The first of these risk areas that the FSIS auditors reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Nicaragua's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, and except as noted below, Nicaragua's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in all three establishments were found to meet the basic FSIS regulatory requirements.

Additionally, in two establishments, the following implementation deficiencies were identified:

- In one establishment, condensation was observed above exposed carcasses in a cooler. The condensation problem had been documented in the September 2003 (monthly) internal review report. Replacement of old insulation and ceiling tiles was programmed, but problems were continuing, and there was very little documentation by the establishment of daily condensation control and corrective measures when product was affected. The MAG-FOR officials ordered the affected carcasses to be trimmed and rejected the cooler for use until the condensation problem is resolved.
- In one establishment, documentation of operational sanitation activities by the establishment was inadequate (only checks of sterilizer temperatures and noting the occasional deficiency were documented).
- In one establishment, preventive measures were not documented as part of the corrective actions taken regarding deficiencies identified by the establishment during pre-operational sanitation.

9.2 Sanitation

The following deficiencies were also noted:

- In one establishment, there were several points on the slaughter floor where carcasses were contacting adjacent equipment with the potential for cross-contamination.
- In one establishment, employees with open containers of inedible materials and employees with open edible product containers were passing through the same strip curtain, with considerable potential for cross-contamination.
- In one establishment, all waste containers (for paper towels) on the slaughter floor and the majority of those in the boning room had hand-operated lids, with the potential for cross-contamination.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditors determined that Nicaragua's inspection system had adequate controls in place. No deficiencies regarding animal disease controls were observed in any of the three establishments.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditors reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, and processing equipment and records.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the three establishments. In all three, the basic HACCP requirements had been adequately implemented.

Additionally, the following implementation deficiencies were identified:

- In one establishment, verification of the monitoring for one of the two critical control points was not documented by the establishment.

11.3 Testing for Generic *E. coli*

Nicaragua has adopted the FSIS regulatory requirements for testing for generic *E. coli*.

All three establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

In all three establishments, the following deficiency was noted:

- In all three establishments, the requirement to develop statistical process control procedures to analyze the results of their testing programs for generic *E. coli* had not been understood; the method intended for excision sampling was being used. It was noted, however, that the upper limit employed - 100 CFU (colony-forming units) /cm² - had been officially recommended to all three establishments in Nicaragua that were certified for U.S. export by the government-owned and -operated National Laboratory of Veterinary Diagnostics where the samples are analyzed.

11.4 Testing for *Listeria monocytogenes*

Testing for *Listeria monocytogenes* was not required because none of the three establishments certified for U.S. export produced any ready-to-eat products.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting,

tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The government-owned and -operated *Laboratorio Nacional de Residuos Químicos y Biológicos* (National Laboratory for Chemical and Biological Residues) in Managua was audited. No deficiencies were noted.

The government-owned and -operated *Laboratorio Nacional de Diagnosticos Veterinarios* (National Laboratory of Veterinary Diagnostics) in Managua was audited. The following deficiency was noted:

- Neither the number of CFUs inoculated into check samples nor the specific strains that were used had been determined.

Nicaragua's National Residue Testing Plan for 2003-04 was being followed and was on schedule.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily and was well-documented in all three establishments.

13.2 Testing for *Salmonella* Species

Testing for *Salmonella* species was properly conducted in all three establishments.

13.3 Species Verification

At the time of this audit, Nicaragua was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly reviews of certified establishments were being performed and documented, as required, in all months in which U.S.-eligible production was conducted.

13.5 Inspection System Controls

In all three establishments, except as noted below, the CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

The following deficiencies were identified:

- In one establishment, atlantal (lateral retro-pharyngeal) lymph nodes were not included in routine post-mortem inspection of beef heads, as required by FSIS.
- In one establishment, the light in abdominal cavities was only 20 foot-candles. FSIS requires 50 foot-candles of shadow-free light at inspection surfaces.

Furthermore, controls were in place for further processing, security items, shipment security, and products entering the establishments from outside sources.

The following deficiencies regarding enforcement were identified:


In all three establishments, deficiencies were observed that should have been identified by MAG-FOR prior to this FSIS audit:

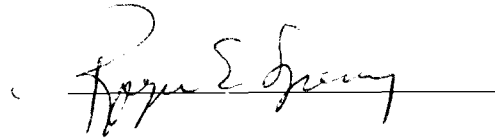
- Condensation previously identified and not corrected (in one establishment).
- Inadequate documentation of operational sanitation activities (in one establishment).
- Inadequate documentation of preventive measures for pre-operational sanitation deficiencies (in one establishment).
- Inadequate light at an inspection station (in one establishment).
- Potential for cross-contamination in three areas of one establishment.

14. CLOSING MEETING

A closing meeting was held on November 19, 2003, in Managua with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the lead auditor.

The CCA understood and accepted the findings.

 Gary D. Bolstad, DVM
International Audit Staff Officer



15. ATTACHMENTS

Individual Foreign Laboratory Audit Forms
Individual Foreign Establishment Audit Forms
Foreign country response to Draft Final Audit Report

FOREIGN COUNTRY LABORATORY REVIEW

11.11.2003

Laboratorio Nacional de Residuos Químicos y
Biológicos

FOREIGN GOV'T AGENCY
Ministerio Agropecuaria y Forestal

CITY & COUNTRY
Managua, Nicaragua

ADDRESS OF LABORATORY
En el Central 300m al Sur

NAME OF REVIEWER
Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL
Dr. Norman Valdivia, Chief Meat Inspector; Dr. Leila Umaña, Laboratory Director

Residue Code/Name			chc	abc	op	hm	des	sul	ivm	bmz					
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A				
	Sampling Frequency	02		A	A	A	A	A	A	A	A				
	Timely Analyses	03		A	A	A	A	A	A	A	A				
	Compositing Procedure	04		A	O	O	O	O	O	O	O				
	Interpret Comp Data	05		A	O	O	O	O	O	O	O				
	Data Reporting	06		A	A	A	A	A	A	A					
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A					
	Correct Tissue(s)	08		A	A	A	A	A	Musc .Liv.	Musc	Musc				
	Equipment Operation	09		A	A	A	A	A	A	A	A				
	Instrument Printouts	10		A	A	A	A	A	A	A	A				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	3 ppb	.04				
	Recovery Frequency	12		A	A	A	A	A	A	A	A				
	Percent Recovery	13		A	A	A	A	A	A	A	A				
	Check Sample Frequency	14		A	A	A	A	A	A	A	A				
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A				
	Corrective Actions	16		A	A	A	A	A	A	A	A				
	International Check Samples	17		A	O	A	O	O	O	O	O				
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O	O				
OTHER REVIEW		19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER

Dr. Gary D. Bolstad

DATE

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

11/11/2003

NAME OF FOREIGN LABORATORY

Laboratorio Nacional de Residuos Químicos y
Biológicos

FOREIGN GOV'T AGENCY

Ministerio Agropecuaria y Forestal

CITY & COUNTRY

Managua, Nicaragua

ADDRESS OF LABORATORY

En el Central 300m al Sur

NAME OF REVIEWER

Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL

Dr. Norman Valdivia, Chief Meat Inspector; Dr. Leila Umaña, Laboratory Director

RESIDUE

ITEM NO.

COMMENTS

Abbreviations: CHC = chlorinated hydrocarbons; ABC = antibiotics; OP = organophosphates; HM = heavy metals; DES = diethylstilbestrol; SUL = sulfonamides; LEV = levamisole; IVM = ivermectin; BMZ = benzimidizoles

Scales and balances were calibrated annually by the National Institute of Metrology, a division of the Ministry of Industrial and Commercial Development, but the laboratory was not provided with copies of the calibration reports, so none were available for audit. Volumetric equipment was not being calibrated at the time of this audit; however, a system for doing so was under development. It was noted that major analytical equipment (HPLC, GC, AA, etc) were calibrated annually, and adequate documentation was maintained in the laboratory.

7.29

Nov. 12, 2003

Laboratorio Nacional de Diagnósticos Veterinarios

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY Ministerio Agupecuaria & Forestal (MAG-FOR)	CITY & COUNTRY Managua, Nicaragua	ADDRESS OF LABORATORY Km 3-1/2, Carretera a Masaya
NAME OF REVIEWER Gary D. Bolstad, DVM	NAME OF FOREIGN OFFICIAL Dr. Norman Valdivia, Chief Meat Inspector; Dr. Sonia Mariana García Vilches	

[illegible]

SIGNATURE OF REVIEWER

J. B. Holmes

DATE _____

Nov. 12, 2005

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

Nov. 12, 2003

NAME OF FOREIGN LABORATORY

Laboratorio Nacional de Diagnosticos Veterinarios

4-26

FOREIGN GOV'T AGENCY Ministerio Agropecuaria & Forestal (MAG-FOR)	CITY & COUNTRY Managua, Nicaragua	ADDRESS OF LABORATORY Km 3-1/2, Carretera a Masaya
NAME OF REVIEWER Gary D. Bolstad, DVM	NAME OF FOREIGN OFFICIAL Dr. Norman Valdivia, Chief Meat Inspector; Dr. Sonia Mariana García Vilches	

RESIDUE	ITEM NO.	COMMENTS
		Abbreviations: Ecol = generic <i>E. coli</i> ; Sal = <i>Salmonella</i> species
Both	19	Neither the number of CFUs inoculated into check samples nor the specific strains that were used had been determined.

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Industrial Comercial San Martin S.A. Nandaime	2. AUDIT DATE Nov 10, 2003	3. ESTABLISHMENT NO. 4	4. NAME OF COUNTRY Nicaragua
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.	X	34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 4: Industrial Comercial San Martin S.A., Nandaime, Nicaragua; November 10, 2003.

8/46/51 Condensation was observed above exposed carcasses in cooler #3. The condensation problem had been documented in the September 2003 (monthly) internal review report. Replacement of old insulation and ceiling tiles was programmed, but problems were continuing, and there was very little documentation by the establishment of daily condensation control and corrective measures when product was affected. The MAG-FOR officials ordered the affected carcasses to be trimmed and rejected the cooler for use until the condensation problem is resolved.

28 The establishment had not developed a statistical process control procedure to analyze the results of the testing program for generic *E. coli*; the method intended for excision sampling was being used. It was noted that the upper limit employed (100 cfu/cm²) was recommended to all three establishments in Nicaragua that were certified for U.S. export by the government-owned and -operated Ministry of Agriculture laboratory where the samples are analyzed. The establishment management agreed to either develop a statistical process control procedure or change the sampling to the excision method promptly.

55 Atlantal (lateral retropharyngeal) lymph nodes were not included in routine post-mortem inspection of beef heads. The FSIS auditor explained the requirement; the MAG-FOR officials agreed to implement the additional procedure immediately.

Note: All deficiencies identified during the previous FSIS audit (on April 9, 2003) had been satisfactorily addressed and corrected.

Following a discussion of the observations, the Chief Meat Inspector of Nicaragua issued a Notice of Intent to Delist to the establishment management if the above deficiencies are not corrected within 30 days of this audit.

61. NAME OF AUDITOR

Garv D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

Manjot H. Chaudry

B-2a

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Nuevo Carnic S.A. Managua, Nicaragua	2. AUDIT DATE Nov 6, 2003	3. ESTABLISHMENT NO. 5	4. NAME OF COUNTRY Nicaragua
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	X
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 5, Nuevo Carnic S.A.; Managua, Nicaragua; November 6, 2003.

13/51 (A) Documentation of operational sanitation activities by the establishment was limited to checks of sterilizer temperatures and noting the occasional deficiency. (B) Preventive measures were not documented as part of the corrective actions taken regarding deficiencies identified by the establishment during pre-operational sanitation. The establishment management gave assurances that they would correct these deficiencies promptly. (These deficiencies should have been identified by MAG-FOR prior to this audit.)

19/51 Verification of the monitoring for CCP2 (carcass temperature after 24 hrs in the cooler) was not documented by the establishment. The establishment management gave assurances that they would correct this deficiency promptly. (This deficiency should have been identified by MAG-FOR prior to this audit.)

28 The establishment had not developed a statistical process control procedure to analyze the results of the testing program for generic *E. coli*; the method intended for excision sampling was being used. It was noted that the upper limit employed (100 cfu/cm²) was recommended to all three establishments in Nicaragua that were certified for U.S. export by the government-owned and -operated Ministry of Agriculture laboratory where the samples are analyzed. The establishment management agreed to either develop a statistical process control procedure or change the sampling to the excision method promptly.

40/51 FSIS requires 50 foot-candles (fc) of shadow-free light at inspection surfaces. The light in abdominal cavities was only 20 fc. The MAG-FOR officials ordered prompt installation of more light fixtures to bring it up to compliance by the start of the next day's operations.

Note: All deficiencies identified during the previous FSIS audit (on April 7, 2003) had been satisfactorily addressed and corrected.

Following a discussion of the observations, the Chief Meat Inspector of Nicaragua issued a Notice of Intent to Delist to the establishment management if the above deficiencies are not corrected within 30 days of this audit.

61. NAME OF AUDITOR

Garv D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

Manzoor H. Chaudry

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Macesa Matadero Central S.A. Juigalpa	2. AUDIT DATE Nov 7, 2003	3. ESTABLISHMENT NO. 8	4. NAME OF COUNTRY Nicaragua
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

B-2b

Est. 8, Macesa Matadero Central S.A., Juigalpa, Nicaragua; November 7, 2003.

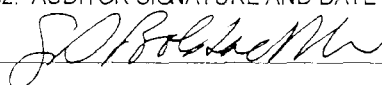
28 The establishment had not developed a statistical process control procedure to analyze the results of the testing program for generic *E. coli*; the method intended for excision sampling was being used. It was noted that the upper limit employed (100 cfu/cm² was recommended to all three establishments in Nicaragua that were certified for U.S. export by the government-owned and -operated Ministry of Agriculture laboratory where the samples are analyzed. The establishment management agreed to either develop a statistical process control procedure or change the sampling to the excision method promptly.

46/51 (A) There were several points on the slaughter floor where carcasses were contacting adjacent equipment with the potential for cross contamination. Those that were movable were immediately moved further away from the carcasses, and the stand that was affixed to the floor was ordered by MAGFOR to be moved after the close of operations on the day of the audit. (B) Employees with open containers of inedible materials and employees with open edible product containers were passing through the same strip curtain, with the potential for cross-contamination. The MAG-FOR officials ordered the strip curtain to be removed immediately. (C) All waste containers (for paper towels) on the slaughter floor and the majority of those in the boning room had hand-operated lids, with the potential for cross-contamination. The lids were immediately removed and discarded. (These deficiencies should have been identified by MAG-FOR prior to this audit.)

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE



11/7/03

[SEAL]

GOVERNMENT OF NICARAGUA
Agriculture, Livestock, and Forests Ministry
Division of Agriculture and Livestock Protection and Health

[SEAL]

Managua, March 15, 2004

[POST-IT NOTE IN RIGHT
MARGIN]

Ms.
Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs
USDA/FSIS

Dear Ms. Stratmoen:

I would like to inform you of the following measures that have been taken, both officially and by the facilities authorized to export to your country (*San Martin, Facility #4, Nuevo Carnic, Facility #5, and MACESA, Facility #8*), in response to your letter of March 5 2004.

- I. **Inadequate implementation of FSIS requirements for risk analysis of critical monitoring points (HACCP) and SSOP procedures.**
 - a) Inclusion of documents to date with corrections and validation to the HACCP Plan.
 - b) On the critical point monitoring page, #1, in column #3, section A, there is zero visual contamination of fecal origin and ingested.
 - c) All the esophagi, rectums, and duodenum correctly nullified and with no rupture in the hymen, small and large intestine, gall bladder, and urinary bladder.
 - d) In the PCC-1, there is current monitoring of 10% of the cattle lots to be slaughtered, and the procedure for selecting the beef to be monitored is being carried out through a random statistical process.
 - e) In the case of the PCC-1, verifications are being carried out to establish proper performance of the monitoring, critical limits, and the application of corrective and preventive measures in cases where deviations occur.
 - f) In the PCC-1 and PCC-2, in addition to the corrective actions taken, preventive actions have also been included.
 - g) In the PCC-2, carcass temperatures of lower than 45o F were included and environmental temperatures lower than 40o F.

[SEAL]

GOVERNMENT OF NICARAGUA

[SEAL]

Agriculture, Livestock, and Forests Ministry

Division of Agriculture and Livestock Protection and Health

- h) All cleaning and sanitation procedures are now included in the SSOP document.
- i) In the SSOP #2, cleaning and sanitation procedures were established for contact surfaces (rust-proof steel sheets on the platforms in the slaughtering room).
- j) The document includes the exact place where generic E. coli is sampled for.

II. Insufficient documentation of the preventive measures as part of corrective actions during the revision of pre-operational sanitation.

- a) Preventive measures were included for each action in accordance with the pre-operational inspection. These preventive actions are include in each SSOP key.
- b) In the event of pre-operational deviations, these are noted in the SSOP format.

III. Insufficient documentation of operational sanitation activities.

- a) The operational sanitation procedures and activities are included in the SSOP. In the event of deviations in these procedures, they are documented in the formats.

IV. Failure to develop a statistical process to analyze the results of the generic E. coli testing.

- a) Statistical controls have been implemented to evaluate the results for the monitoring of generic E. coli.

V. Inadequate supervision by the Government of Nicaragua.

- a) All procedures set forth in the Meat Inspection Regulations for authorized facilities are being applied.
- b) The chief of the Meat Inspection Service is carrying out monthly inspection visits in order to perform follow-up supervision and compliance with the official USDA audit.
- c) An official Meat Inspection Commission was formed with the veterinary officials of facilities # 4, 5, and 8. They carry out monthly inspections of any slaughterhouse that is authorized to export to the United States. These visits are documented on a specific form.

[SEAL]

GOVERNMENT OF NICARAGUA
Agriculture, Livestock, and Forests Ministry
Division of Agriculture and Livestock Protection and Health

[SEAL]

- d) The appointment of an assistant chief of the Meat Inspection Service, to provide professional and technical support to the duties carried out by this service, and to comply with international requirements regarding hygiene, sanitation, and safety of all products processed in facilities authorized to export to the United States.

For all the reasons listed above, I am pleased to inform you that all the deficiencies observed by the FSIS- USDA officials have been rectified. I am attaching a document regarding the corrective measures taken with note DICH-DVP.0349-03 dated December 9, 2003.

With nothing further for the moment, I remain,

Yours sincerely,

[SEAL]

[SIGNATURE]

Diego Velásquez Pereira
HACCP Inspection and Certification Department Head

[SEAL]

[SIGNATURE]

Norman Valdivia Quijano
Chief of Meat Inspection

Cc: Dr. Denis Salgado Fonseca	--- Director General IXTPSA
Dr. Omar García Corrales	--- Director of Animal Health
Eng. Diego Velasquez Pereira	--- Chief of Department of Inspection and Certification
Mr. Ervin F. Leiva	--- Agricultural Specialist
File copy	

DIVISION OF ANIMAL HEALTH/DEPARTMENT OF INSPECTION AND CERTIFICATION/HACCP
Km. 3 ½. road to Macaya. Fax 276-0243 Facility 278-3418, 2278-4235 Ext. 107 E-mail: haccp@mugfor.gob.ni
Managua, Nicaragua